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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,062	05/10/2002	A Satyanarayan Naidu	50046290-0007	9560

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/980,062	NAIDU, A SATYANARAYAN	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2004 and 07 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49,51 and 56-202* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *6-10,14-17,40-49,51,59-61,63,66,67,69-85,91,93-100 and 118* is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *See Continuation Sheet* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 1,2,5,11,18-20,22,28,31,32,38,39,86,101-104,106,115-117,119-124,126-129,131-138,142-151,153,154,157-159,162-165,171-173,175,176,179-181,184-187,193-197 and 200-202.
Continuation of Disposition of Claims: Claims objected to are 3,4,12,13,21,23-27,29,30,33-37,56-58,62,64,65,68,87-90,92,105,107-114,125,130,139-141,152,155,156,160,161,166-170,174,177,178,182,183,188-192,198 and 199.

1. The amendments to the specification at page 10, lines 19-22, and at page 10, line 35 - page 11, line 3, filed February 7, 2005 fail to comply with 37 CFR 1.121(b) (1)(ii) because deletions and insertions have been made to the texts of the paragraphs without the changes being marked by underlining and strikethrough. While a replacement for the paragraph at page 12, lines 2-24, has been submitted, the examiner can not locate any amendment markings, nor can the examiner identify any unmarked changes which might have been made to this paragraph. The amendments to claims 2, 19, 20, 36, 104, and 187 fail to comply with 37 CFR 1.121(c)(2) because deletions and insertion have been made to the texts of the paragraphs without the changes being marked by underlining and strikethrough and because, in the case of claim 187, a comma at line 6 is underlined even though the comma was present in the previous version of the claim.

No proposed amendment after final rejection will be entered unless it completely complies with the amendment format rules set forth in 37 CFR 1.121.

2. The claim for priority inserted at page 1, lines 5-6, of the specification by the preliminary amendment filed November 28, 2001 is objected to because it is not the first sentence of the specification. Further, the claim for priority is objected to because it does not use appropriate language for claiming the benefit of a PCT application under 35 U.S.C. 371 and because it does not use appropriate language for claiming the benefit of a non-provisional application (e.g., continuation, divisional, continuation-in-part). See MPEP 201.11 (III).

The amendment submitted February 7, 2005 did not contain any response to this objection. Note that the amendment filed July 19, 2004, which did contain a response to this Office action, was not entered.

Correction is required.

3. Claims 86 and 120-122 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claims for the phrase "the composition" at claim 86, line 2. Note that at line 1 of the claim, "composition" was changed to "foodstuff". There is no antecedent basis in the claims for the phrase "the cosmetic, cleanser, food supplement, or medicament" in claim 120. It is believed that claim 120 should instead depend upon claim 119.

4. Claims 20, 36, and 104 are objected to because of the following informalities: At claim 20, line 2, and at claim 104, line 2, the comma after "including" should be deleted. At claim 36, line 2, spaces should be re-inserted between "Clostridium" and "difficile" and between "Clostridium" and "botulinum". Appropriate correction is required.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1, 2, 11, 18, 19, 28, 31, 38, 39, 101-103, 119-124, 126-129, 131, 132, 134, 142-148, 197, and 200 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 91/13982. The WO Patent Application '982 teaches lactoferrin in combination with stearic acid (which is a lipid and also corresponds to Applicant's pharmaceutically acceptable carrier of claim 102) or its salts. The composition is used as an antiseptic. Lactoferrin concentrations on the surfaces to be treated are 0.1-1 mg/6 cm^2 (approximately equal to 0.1-1 mg/in^2). Buffers can be present in the antiseptic compositions of the reference. See, e.g., page 7, line 30 - page 9, line 24. Because the same components are present in the same defined

dispersion, inherently the lactoferrin in the composition of the WO Patent Application '982 will be immobilized via its N-terminus to the stearic acid to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the composition of the WO Patent Application '982 and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the composition of the WO Patent Application '982. With respect to instant claims 101, 122-124, 126-129, 131, 132, 134, and 142-148, note that an intended use limitation does not impart patentability to composition claims where the composition is otherwise anticipated by or obvious over the prior art, and that these claims do not structurally or functionally limit the claimed compositions so as to distinguish over those taught by the WO Patent Application '982.

7. Claims 149-151, 153, 164, 171-173, 175, 186, and 193-195 are rejected under 35 U.S.C. 103(a) as being obvious over the WO Patent Application 91/13982. Application of the WO Patent Application '982 is the same as in the above rejection of claims 1, 2, 11, 18, 19, 28, 31, 38, 39, 101-103, 119-124, 126-129, 131, 132, 134, 142-148, 197, and 200. The WO Patent Application '982 teaches administering its antiseptics to mammals, but does not particularly teach treating humans or non-human vertebrates. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to use the antiseptic compositions of the WO Patent Application '982 to treat both human and non-human mammals because it is desirable to treat both human and non-human mammals with antiseptics and because the activity of the antiseptic compositions of the WO Patent Application '982 would not have been expected to be affected by the subject being treated, but rather would have been expected to have general utility regardless of where the source of microbial contamination is found.

8. Claims 1, 2, 5, 18, 19, 22, 31, 101-103, 106, 115-117, 119-124, 126-129, 131-132, 134, 136, 142-151, 153, 164, 171-173, 175, 186, 193-197, and 200-202 are rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent Application 753,309. The European Patent Application '309 teaches compositions comprising lactoferrin and carriers such as paraffin oil and Vaseline (which are lipids), xantan gum and corn starch (which are polysaccharides), and lecithin (which is an emulsifier). The compositions are in the form of ointments, creams, gels, and powders The compositions are used to prevent or treat viral infections on the skin or mucosae of humans or animals. See, e.g., the Abstract; Examples 5-8; and claim 1. Because the same components are present in the same defined dispersion, inherently the lactoferrin in the composition of the European Patent Application '309 will be immobilized via its N-terminus to the paraffin oil, Vaseline, xantan gum, and corn starch to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the composition of the European Patent Application '309 and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the composition of the European Patent Application '309. With respect to instant claim 101, an intended use limitation does not impart patentability to product claims which are otherwise anticipated by or obvious over the prior art.

9. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being obvious over the European Patent Application 753,309. Application of the European Patent Application '309 is the same as in the above rejection of claims 1, 2, 5, 18, 19, 22, 31, 101-103, 106, 115-117, 119-124, 126-129, 131-132, 134, 136, 142-151, 153, 164, 171-173, 175, 186, 193-197, and 200-202. The European Patent Application '309 does not teach a lactoferrin/surface area ratio for the

surfaces to be treated. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal doses for the lactoferrin-containing compositions of the European Patent Application '309 because dose is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

10. Claims 1, 2, 5, 18, 19, 22, 31, 32, 101-103, 106, 115, 119-124, 126-129, 131-136, 142-151, 153, 159, 162-165, 171-173, 175, 181, 184-187, 193-197, and 200-202 are rejected under 35 U.S.C. 102(b) as being anticipated by the European Patent Application 753,308. The European Patent Application '308 teaches compositions comprising lactoferrin and peppermint oil, gum base and corn starch (which are polysaccharides), glucose, and additional antibiotic compounds such as erytromicin and ampicillin. The compositions are in the form of gargles, aqueous solutions, chewing gum, and powders The compositions are used to prevent or treat bacterial infections such as by S. aureus and S. pyogenes on the skin or mucosae of humans or animals. See, e.g., the Abstract; Examples 5-8; and the claims. Because the same components are present in the same defined dispersion, inherently the lactoferrin in the composition of the European Patent Application '308 will be immobilized via its N-terminus to the peppermint oil, gum base, and corn starch to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the composition of the European Patent Application '308 and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the composition of the European Patent Application '308. With respect to instant claim 101, an intended use limitation does not

impart patentability to product claims which are otherwise anticipated by or obvious over the prior art.

11. Claims 38 and 39 are rejected under 35 U.S.C. 103(a) as being obvious over the European Patent Application 753,308. Application of the European Patent Application '308 is the same as in the above rejection of claims 1, 2, 5, 18, 19, 22, 31, 32, 101-103, 106, 115, 119-124, 126-129, 131-136, 142-151, 153, 159, 162-165, 171-173, 175, 181, 184-187, 193-197, and 200-202. The European Patent Application '308 does not teach a lactoferrin/surface area ratio for the surfaces to be treated. It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to determine all operable and optimal doses for the lactoferrin-containing compositions of the European Patent Application '308 because dose is an art-recognized result-effective variable which is routinely determined and optimized in the pharmaceutical arts.

12. Claims 1-3, 5, 18-20, 22, 31, 32, 102-104, 106, 115, 119, 124, 137, 138, 142-150, 154, 164, and 165 are rejected under 35 U.S.C. 102(e) as being anticipated by Kruzel et al (U.S. Patent No. 6,066,469). Kruzel et al teach nutritional supplements comprising lactoferrin in combination with adjuvants or diluents such as cellulose, starch, gelatin, tragacanth, and sodium carboxymethylcellulose. Lactoferrin acts to treat or prevent bacterial, viral, and fungal infections, such as S. pneumoniae infections. See, e.g., column 6, lines 40-56, and column 8, line 47 - column 9, line 7. Because the same components are present in the same defined dispersion, inherently the lactoferrin in the nutritional supplements of Kruzel et al will be immobilized via its N-terminus to the carriers or diluents to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the compositions of

Kruzel et al and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the compositions of Kruzel et al. With respect to instant claims 144-148, an intended use does not impart patentability to composition claims where the composition is otherwise anticipated by or obvious over the prior art.

13. Claims 102-104, 115-117, 119, 124, 127, 128, 137, 138, 142-148, 154, 157, 158, 171, 172, 176, 179, 180, 186, and 193-196 are rejected under 35 U.S.C. 102(e) as being anticipated by Gohlke et al (U.S. Patent No. 6,475,511). Gohlke et al teach lactoferrin combined with colostrum (which inherently contains proteins such as casein, polysaccharides, lipids, lactose, cholesterol, physiological emulsifiers, monoglycerides, and diglycerides), pectin (which is a polysaccharide), and pharmaceutically acceptable carriers such as dextrose (see, e.g., Examples 1-3). The components are thoroughly mixed and cold pressed to form a lozenge. The lozenges are administered to the oral mucosa, whereby the lactoferrin is absorbed and enters the bloodstream and inhibits infections in mammals, especially humans (see, e.g., the abstract). Because the same components are present in the same compositions, inherently the lactoferrin in the lozenges of Gohlke et al will be immobilized via its N-terminus to the proteins, polysaccharides, and lipids which are present to the same extent claimed by Applicant. Sufficient evidence of similarity is deemed to be present between the compositions of Gohlke et al and Applicant's claimed composition to shift the burden to Applicant to provide evidence that the claimed composition is unobviously different than the compositions of Gohlke et al. With respect to instant claims 142-148, an intended use does not impart patentability to composition claims where the composition is otherwise anticipated by or obvious over the prior art.

Gohlke et al is available as prior art against instant claims 102-104, 115-117, 119, 124, 127, 128, 137, 138, 142-148, 154, 157, 158, 171, 172, 176, 179, 180, 186, and 193-196 because these claims are not entitled under 35 U.S.C. 120 to the benefit of the filing date of grandparent application 09/322,700. These claims are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of the grandparent application '700 because the grandparent application '700, under the test of 35 U.S.C. 112, first paragraph, does not disclose pharmaceutically acceptable carriers, does not disclose systemic administration, does not disclose administration through a transmucosal delivery route, does not disclose ingestive delivery systems such as lozenges, and does not disclose administering to non-human vertebrates in general.

For other claims whose subject matter may be taught or suggested by Gohlke et al, i.e. claims 1-3 and 18, these other claims are deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of grandparent application 09/322,700. The subject matter of Gohlke et al, and especially that subject matter relied upon in the above rejection, is not deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/096,697, and therefore Gohlke et al is not available as prior art against these other claims.

14. Applicant's arguments filed August 2, 2004 and February 7, 2005 have been fully considered but they are not persuasive.

Applicant did not respond to the rejection of claim 86 under 35 U.S.C. 112, second paragraph.

The declaration by Barron under 37 CFR 1.132 filed August 2, 2004 performs no direct testing on the prior art compositions in order to determine whether or not they comprise lactoferrin immobilized to a naturally occurring substrate via the N-terminus region of the

lactoferrin. Instead, the declaration and Applicant's Remarks attempt to show by scientific reasoning and/or argument that the prior art compositions do not teach this feature. However, because the reasoning has an insufficient factual basis and/or contradicts the disclosure set forth in Applicant's specification, it is insufficient to rebut the prima facie case of anticipation.

One major argument made by Declarant and in the Remarks is that "[f]or the N-terminus region to become immobilized on a naturally occurring substrate, the region of the substrate to which the N-terminus region is to become attached should carry the opposite charge, i.e., carry a negative charge." See the Declaration at paragraph 9. [The statement at page 36, lines 7-9, of the Remarks that the substrate must carry a positive charge is an obvious error.] However, Declarant does not provide any citation to the specification which would support this contention, and the examiner can find no support in the original disclosure of the invention for this contention. Further, this argument is inconsistent with the disclosure in the specification of useful substrates which do not have a positive charge. For example, the original specification at page 10, line 22, and originally-filed claim 3 disclose triglycerides to be useful substrates for immobilizing lactoferrin by its N-terminus region. Triglycerides are uncharged. The original specification at page 10, lines 19-22, and originally-filed claim 3 disclose proteins, polysaccharides, and lipids to be useful substrates for immobilizing lactoferrin by its N-terminus. These classes of compounds embrace positively charged, negative charged, and uncharged compounds. To the extent that the opinions set forth in the declaration are contradicted by the specification, they can not be relied upon to rebut the prima facie case of anticipation. Finally, this argument by Declarant uses a significant qualifier "should". Because of the use of this word, Declarant in effect admits that a substrate does not have to have a negative charge in order to be

useful in immobilizing lactoferrin by its N-terminus. Accordingly, this argument does not rebut the prima facie case of anticipation.

With respect to Gohlke et al (U.S. Patent No. 6,475,511), Declarant argues that mixing and cold pressing as occurs in Gohlke et al will not provide an environment suitable to cause the lactoferrin to become attached to the colostrum or the modified pectin via the lactoferrin's N-terminus region. However, Declarant does not provide any reasoning or evidence as to why these processing steps of Gohlke et al are insufficient to result in immobilization via the N-terminus of lactoferrin. Further, there is no disclosure anywhere in the specification that special procedures or conditions are necessary in order to achieve the desired immobilization. See, e.g., page 11, lines 3-11, of the specification. In the absence of a disclosed need for special conditions, Gohlke et al's disclosed thorough mixing and cold pressing of the ingredients in powder form is deemed to be sufficient to result in the claimed immobilization.

With respect to the WO Patent Application 91/13982, Declarant argues that stearic acid is not a substrate because of its low molecular weight. This argument can not be accepted because it contradicts the original disclosure of substrates with molecular weights significantly less than that of lactoferrin. For example, page 10, lines 19-22, of the specification and originally-filed claim 3 recite that nucleic acids, nucleotides, lipids, adenosine triphosphate, and triglycerides are all useful and acceptable substrates. These exemplified substrates have molecular weights which are significantly less than that of lactoferrin. Accordingly, stearic acid can not be disqualified as a substrate merely because of its molecular weight. Declarant also argues that mere compounding will not result in lactoferrin's attachment to the stearic acid through the N-terminus of the lactoferrin. However, Declarant does not provide any reasoning or evidence to

support this argument, and there is no disclosure any where in the specification that special procedures or conditions are necessary in order to achieve the desired immobilization. Further, because stearic acid has a negatively charged carboxyl group, all that it would take for the positively charged N-terminus of lactoferrin to become immobilized on the negatively charged carboxyl group would be to bring the two opposite charges into close physical proximity - charge attraction will do the remainder of the work. Any pharmaceutical compounding step will provide the necessary physical proximity so that at least some of the lactoferrin is immobilized by its N-terminus to a least some of the stearic acid.

Declarant and Applicant in the remarks make the same arguments with respect to the European Patent Application 753,309, the charge and size of the substrates, and the necessity for special immobilization procedures, as have already been discussed above. In addition, Declarant and Applicant contend that paraffin oil and Vaseline are not lipids. However, Biedermann et al (U.S. Patent No. 6,444,823 at column 131, lines 17-23) and Groteluschen et al (U.S. Patent Application Publication 2005/0025729 at paragraph [0044]) teach that Vaseline and paraffin oil are lipids.

Declarant and Applicant in the remarks make the same arguments with respect to the European Patent Application 753,308, the charge and size of the substrates, and the necessity for special immobilization procedures, as have already been discussed above.

Declarant and Applicant in the remarks make the same arguments with respect to Kruzel et al (U.S. Patent No. 6,066,469), the charge of the substrates, and the necessity for special immobilization procedures, as have already been discussed above.

15. Claims 6-10, 14-17, 40-49, 51, 59-61, 63, 66, 67, 69-85, 91, 93-100, and 118 are allowed. Claims 3, 4, 12, 13, 21, 23-27, 29, 30, 33-37, 56-58, 62, 64, 65, 68, 87-90, 92, 105, 107-114, 125, 130, 139-141, 152, 155, 156, 160, 161, 166-170, 174, 177, 178, 182, 183, 188-192, 198, and 199 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 36 would be allowable if rewritten to overcome the claim objections set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Claim 86 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

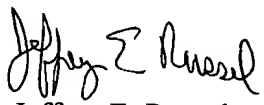
16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The

examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.



Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

April 4, 2005